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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,922	06/07/2006	Philippe Boutin	Q88618	5674

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EXAMINER	
KAPUSHOC, STEPHEN THOMAS	
ART UNIT	PAPER NUMBER
1634	
MAIL DATE	DELIVERY MODE
04/16/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/538,922	BOUTIN ET AL.	
	Examiner	Art Unit	
	Stephen Kapushoc	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *one* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-22* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1 and 2, and 5 in part as it depends from claim 1 or 2, drawn to methods for diagnosing a predisposition to diabetes comprising analysis of nucleic acid alteration.

Group 2, claim(s) 4 in part as it requires investigating the level of an expression product that is RNA, and 5 in part as it depends from claim 3 or 4, drawn to methods for diagnosing a predisposition to diabetes comprising analysis of the level of an expression product.

Group 3, claim(s) 4 in part as it requires investigating the level of an expression product that is protein, and 5 in part as it depends from claim 3 or 4, drawn to methods for diagnosing a predisposition to diabetes comprising analysis of the level of an expression product.

Group 4, claim(s) 4 in part as it requires investigating the level of an expression product that is GABA, and 5 in part as it depends from claim 3 or 4, drawn to methods for diagnosing a predisposition to diabetes comprising analysis of the level of an expression product.

Group 5, claim(s) 6-8, drawn to oligonucleotides and kits comprising oligonucleotides.

Group 6, claim(s) 9-11, drawn to drug screening methods requiring the GAD2 polypeptide.

Group 7, claim(s) 12 and 13, drawn to drug screening methods requiring the gad2 gene.

Group 8, claim(s) 14, drawn to a pharmaceutical compound.

Group 9, claim(s) 15-17, drawn to methods of drug preparation including nucleic acids complementary to gad2 mRNA.

Group 10, claim(s) 18, drawn to methods of drug manufacture comprising the 5' flanking region of the gad2 gene.

Group 11, claim(s) 19-21, drawn to transgenic mammals in which the gad2 gene is modified.

Group 12, claim(s) 22, drawn to methods for studying obesity comprising a mammal in which the gad2 gene is modified.

Linking Claim

Claim 3 link(s) inventions 2, 3 and 4. Claim 3 is generic with regard to the detection of an expression product, whereas the inventions of groups 2, 3, and 4 specify a particular expression product. The restriction requirement among the linked inventions is **subject to** the nonallowance of the linking claim(s), claim 3. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Additional Lack of Unity Requirement:

If Applicants elect the invention of Group 5, Applicants shall further elect a signle specific combination of sequences from the group consisting of: (i) SEQ ID NO: 4, 5, 8, 9, 12 and 13; or (ii) SEQ ID NO: 6, 7, 10, 11, 14, and 15 (relevant to claim 7). Applicants shall also further select a single particular sequence from the group consisting of SEQ ID NO: 4-15 (relevant to claim 6); the selected single sequence should be a sequence form the selected particular combination of sequences, (i) or (ii) above. Applicants shall also further select a single particular sequence from SEQ ID NO: 16 or 17 (relevant to claim 8).

2. The inventions listed as Groups 1-12 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

3. The common technical feature among Groups 1-12 is the gad2 gene and encoded polypeptide. However, this feature was known in the prior art. Johnson et al (2002) teaches that "The entire contiguous genomic sequence of GAD2 can be found on a clone from the RPCI-13 BAC library, RP13-8106: AL389927 (available at www.sanger.ac.uk). The coding regions of GAD2 are organized into 16 exons spanning 88 kb, and the sequence and genomic structure of rat, murine, and human GAD2 genes appears to be highly conserved." (p.2866, right col., last paragraph). Thus the gad2 gene, the protein-coding portion of the gene, and the encoded GAD2 polypeptide were know in the prior art.

Regarding the Additional Lack of Unity Requirement, the different oligonucleotide sequences, and combinations thereof, are different because they are composed of unique structures. They are composed of different sequences of nucleotide monomers, and thus constitute chemical structures that are distinct and not common to one another.

4. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Kapushoc whose telephone number is (571)272-3312. The examiner can normally be reached on Monday through Friday, from 8am until 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Stephen Kapushoc/
Primary Examiner, Art Unit 1634